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510(k) Summary
EVIS EXERA Colonovideoscopes CF-Q160 AL/I and PCF-160 AL/I

A. Submitter's Name, Address, Phone and Fax Numbers

1. Manufacturer of subject device

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 2-3-1 Shinjyuku Monolis Nishishinjyuku Shinjuku-ku, Tokyo, Japan
Registration number:	8010047
Address, Phone and Fax numbers of R&D department, Endoscope division:	2951 Ishikawa-Cho Hachioji-shi, Tokyo 192-8507 telephone (426) 42-5101 Facsimile (426) 46-2786

B. Name of Contact Person

Name: Address, Phone and Fax numbers:	Laura Storms-Tyler Olympus America Inc. Director, Regulatory Affairs Two Corporate Center Drive Melville, NY 11747-3157 Telephone (516) 844-5688 Facsimile (516) 844-5416

C. Device Name, Common Name, Classification Name and Predicate Devices

Device Name:	Olympus EVIS EXERA Colonovideoscopes CF-Q160 AL/I and PCF-160 AL/I
Common Name:	Endoscopic Video Information System
Classification Name:	Endoscope and accessories 21 CFR 876.1500, Class II

Summary Preparation Date: April 17, 2000

D. Device Description:

The EVIS EXERA Colonovideoscopes CF-Q160 AL/I and PCF-160 AL/I have been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories such as biopsy forceps and ancillary equipment.

The modifications to these devices is to provide a control mechanism to the endoscopes which allows the user the ability to vary the stiffness of the insertion tube, as a means of aiding the physician in inserting the colonoscope into the human colon.

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E. Statement of Intended Use

The CF-Q160 AL/I and the PCF-160 AL/I are intended for endoscopy and endoscopic surgery within the lower digestive tract (including the anus, rectum, sigmoid colon, colon and ileocecal valve).

F. Summary including Conclusions drawn from Non-Clinical Tests

When compared to similar devices, the EVIS EXERA Colonovideoscopes CF-Q160 AL/I and PCF-160 AL/I do not incorporate any significant changes in intended use, material or design that could affect safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2000

Olympus Optical Co., LTD
c/o Ms. Laura Storms-Tyler
Director, Regulatory Affairs and
Quality Assurance
Olympus America Inc.
Two Corporate Center Drive
Melville, NY 11747

Re: K001241
EVIS EXERA Colonovideoendoscopes
Dated: April 17, 2000
Received: April 18, 2000
Regulatory Class: II
21 CFR §876.1500/ Procode: 78 FDF

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (If known): K001241

Device Name: EVIS EXERA Colonovideoendoscopes

Indications for Use:

The EVIS EXERA Colonovideoscopes CF-Q160 AL/I and the PCF-160 AL/I are intended for endoscopy and endoscopic surgery within the lower digestive tract (including the anus, sigmoid colon, colon and ileocecal valve).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001241